



PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference UAB-20852/22	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/US03/17271	International filing date (day/month/year) 03 June 2003 (03.06.2003)	Priority date (day/month/year) 03 June 2002 (03.06.2002)
International Patent Classification (IPC) or national classification and IPC IPC(7): A61K 38/43 and US Cl.: 424/94.1, 94.64, ; 514/165		
Applicant UAB RESEARCH FOUNDATION		

- This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
- This REPORT consists of a total of 4 sheets, including this cover sheet.
☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of ___ sheets.

- This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of report with regard to novelty, inventive step and industrial applicability
- IV ☒ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 30 December 2003 (30.12.2003)	Date of completion of this report 10 September 2004 (10.09.2004)
Name and mailing address of the IPEA/US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Authorized officer <i>Valerie Bell-Harris</i> Ruth A. Davis Telephone No. (571)272-1600

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

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I. Basis of the report

1. With regard to the elements of the international application:*

☒ the international application as originally filed.

☒ the description:

pages 1-18 _____ as originally filed

pages NONE _____, filed with the demand

pages NONE _____, filed with the letter of _____.

☒ the claims:

pages 19-24 _____, as originally filed

pages NONE _____, as amended (together with any statement) under Article 19

pages NONE _____, filed with the demand

pages NONE _____, filed with the letter of _____.

☒ the drawings:

pages none _____, as originally filed

pages NONE _____, filed with the demand

pages NONE _____, filed with the letter of _____.

☐ the sequence listing part of the description:

pages NONE _____, as originally filed

pages NONE _____, filed with the demand

pages NONE _____, filed with the letter of _____.

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

☐ the language of publication of the international application (under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in printed form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☒ The amendments have resulted in the cancellation of:

☒ the description, pages none

☒ the claims, Nos. none

☒ the drawings, sheets/fig none

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

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IV. Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees the applicant has:

- ☐ restricted the claims.
- ☒ paid additional fees.
- ☐ paid additional fees under protest.
- ☐ neither restricted nor paid additional fees.

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention is accordance with Rules 13.1, 13.2 and 13.3 is

- ☐ complied with.
- ☒ not complied with for the following reasons:

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I, claims 1 - 25, 36 and 38, drawn to a process for reducing cerebrospinal fluid flow obstructions.

Group II, claims 26 - 35 and 37, drawn to a kit.

The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the claims do not contain a special technical feature which contributes over the prior art. Specifically, kits comprising heparin (a clot reducing agent) are known in the art (see US 6146874 A).

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

- ☒ all parts.
- ☐ the parts relating to claims Nos. _____

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V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. STATEMENT

Novelty (N)

Claims 1-38 YES
Claims NONE NO

Inventive Step (IS)

Claims 1-38 YES
Claims NONE NO

Industrial Applicability (IA)

Claims 1-38 YES
Claims NONE NO

2. CITATIONS AND EXPLANATIONS

Claims 1 - 38 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest reducing cerebral spinal fluid flow obstructions by administering a clot reducing drug to subjects who exhibit obstructive hydrocephalus symptoms. In addition, kits comprising the clot reducing drugs are not disclosed in the prior art for reducing obstructive hydrocephalus.

Claims 1 - 38 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.